DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 4, 2015

Spectranetics, Inc.
Christopher McLellan
Senior Regulatory Specialist
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K150360
Trade/Device Name: TightRail Rotating Dilator Sheath, TightRail Mini Rotating Dilator Sheath
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: February 11, 2015
Received: February 13, 2015

Dear Christopher McLellan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150360

Device Name

TightRail and TightRail Mini Rotating Dilator Sheaths

Indications for Use *(Describe)*

The TightRail and TightRail Mini Rotating Dilator Sheaths are intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters, and foreign objects

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92

Prepared on 11 February 2015

510(k) Submitter / Holder:

Spectranetics
9965 Federal Drive
Colorado Springs, CO 80921-3617
Establishment Registration No: 3007284006

Contact:

Christopher S. McLellan
Sr. Regulatory Specialist
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Email: christopher.mclellan@spnc.com

Subject Device

Device Trade Name:	TightRail and TightRail Mini Rotating Dilator Sheaths
Device Common Name:	Sheath
Device Class:	II
Classification Regulation:	21 CFR 870.1310
Regulation Description:	Vessel dilator for percutaneous catheterization
Product Code:	DRE
510(k) Type:	Special
Model Numbers:	545-009, 545-011, 545-013, 540-009, 540-011

Predicate Device

The TightRail Mini was compared to the following legally marketed predicate device:

510(k) Number:	K142546
Manufacturer:	Spectranetics
Trade Name:	TightRail and TightRail Mini
Device Common Name:	Sheath
Model Numbers:	545-009, 545-011, 545-013, 540-009, 540-011

Device Description

The TightRail and TightRail Mini Rotating Dilator Sheaths are intra-operative devices. The devices consist of a proximal handle drive mechanism with a distal dilation sheath. Each rotating dilator sheath is packaged with an optional outer support sheath. The dilator sheath is advanced, withdrawn, and rotated about the lead, catheter, or foreign object to be removed. Actuating the trigger on the proximal handle activates a rotary dilation mechanism sheathed at the distal terminus of the dilation sheath. Rotation of the inner shaft is translated to axial actuation of the dilation mechanism via a cam path contained within the distal components. Actuation of the distal dilation mechanism causes dilation of tissue and fibrous attachments surrounding the object targeted for removal thereby facilitating removal of said object. For the TightRail the diameter sizes range from 9 French (F) to 13 F with a nominal effective length of 47.5cm. For the TightRail Mini, the diameter sizes range from 9 French (F) to 11 F with a nominal effective length of 15.5 cm.

Intended and Indications for Use

The TightRail and TightRail Mini Rotating Dilator Sheaths are intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters and foreign objects

Technological Characteristics
The TightRail and TightRail Mini Rotating Dilator Sheaths feature the same performance characteristics as the predicate device (K142546 – TightRail and Tight Rail Mini Rotating Dilator Sheath). There are no significant changes to the function of the device. Changes have been made to material of the trigger pin. The subject and predicate are otherwise identical with regards to technological characteristics.

Performance Data[1]
The following testing was conducted to validate and verify that the subject device met all requirements of as identified in the risk analysis that was performed.

Design Verification and Validation Testing
- Dimensional Verification
- Tri Coil Tensile Test
- Tri Coil Torsional Test
- Axial Load Test
- Outer Sheath Axial Load Test
- Radio-Detectability Test
- Corrosion Resistance Test
- Simulated Use Testing*
- Dimensional Verification at 2 years
- Outer Sheath Axial Load Test at 2 years
- Simulated Use Test at 2 years
- Package Integrity at 2 years
- Simulated Distribution (Shipping and Simulated Environmental Conditioning) Test

Sterilization:
- Product adoption equivalency per AAMI TIR:28-2009

Biocompatibility:
- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- C3a Complement Activation
- SC5b-9 Complement Activation
- Direct Hemolysis
- Indirect Hemolysis
- *In Vivo* Thrombogenicity-Ovine Model
- Genotoxicity – Ames Test
- Material Mediated Pyrogenicity

Preclinical and Clinical Data:
Preclinical and clinical data was not required to demonstrate substantial equivalence. The design characteristics of the subject device are similar to the predicate. The design verification and validation test results demonstrated that the subject device is as safe and clinically effective as the predicate device.

Substantial Equivalence:
Based on the similarities in design between the subject and predicate devices, and the performance testing performed, the TightRail and TightRail Mini Rotating Dilator Sheaths, with the new trigger pin material, are substantially equivalent to the previously cleared TightRail and TightRail Mini Rotating Dilator Sheaths (K142546).

[1] All testing marked with an * is summarized in this submission. All other testing is leveraged from K142546.